STATE OF CALIFORNIA OFFICE OF ADMINISTRATIVE LAW

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AGENCY: BOARD OF CHIROPRACTIC ) DECISION OF DISAPPROVAL
EXAMINERS ) OF REGULATORY ACTION
) (Gov. Code, sec. 11349.3)
) OAL File No. 05-0826-03 S
ACTION: Adopt section 361 of Title 16 )
of the California Code of )
Regulations )
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DECISION SUMMARY

The California Board of Chiropractic Examiners (Board) proposed regulatory amendments to the California Code of Regulations (CCR) to permit licensed chiropractors to perform manipulation under anesthesia (MUA), subject to specified conditions. On August 26, 2005, the regulation was submitted to the Office of Administrative Law (OAL) for review. OAL notified the Board that it had disapproved the regulation on October 5, 2005. OAL disapproved the regulation because provisions of the regulation did not comply with the consistency, authority, necessity, and clarity standards of the Administrative Procedure Act (APA).

DISCUSSION

BACKGROUND

The Board regulates the practice of chiropractic pursuant to authority granted by the Chiropractic Initiative Act of California (Act), an initiative measure approved by the electors on November 7, 1922. Among other things, the Act grants authority to the Board to enforce and administer the Act, to license chiropractors, to establish educational requirements that must be met to become a licensed chiropractor, to approve chiropractic schools and colleges and to adopt such rules and regulations as it deems proper and necessary for the performance of its work. Regulations are required to be adopted pursuant to the requirements of the APA. The Act also establishes limits upon the scope of the practice of chiropractic.

Section 7 of the Act1 is of particular relevance to this regulation. This section provides for the issuance of one form of license to practice chiropractic, authorizes any licensee to practice chiropractic as taught in chiropractic schools and colleges, and authorizes the use of specified incidental measures in the practice of chiropractic. It also specifies restrictions upon legally permissible practices within the practice of chiropractic.

1 § 7. Certificate to practice; issuance; practice authorized: One form of certificate shall be issued by the board of chiropractic examiners, which said certificate shall be designated "License to practice chiropractic," which license shall authorize the holder thereof to practice chiropractic in the State of California as taught in chiropractic schools or colleges; and, also, to use all necessary mechanical, and hygienic and sanitary measures incident to the care of the body, but shall not authorize the practice of medicine, surgery, osteopathy, dentistry or optometry, nor the use of any drug or medicine now or

hereafter included in materia medica.

2 Unless stated otherwise, all California Code references are to the Government Code.

3 § 4. Powers of board

(a) . . .

- (b) To adopt from time to time such rules and regulations as the board may deem proper and necessary for the performance of its work, the effective enforcement and administration of this act, the establishment of educational requirements for license renewal, and the protection of the public. Such rules and regulations shall be adopted, amended, repealed and established in accordance with the provisions of Chapter 4.5 (commencing with Section 11371) of Part 1 of Division 3 of Title 2 of the Government Code as it now reads or as it may be hereafter amended by the Legislature.
- 4 Section 11342.2 provides as follows: Whenever by the express or implied terms of any statute a state agency has authority to adopt regulations to implement, interpret, make specific or otherwise carry out the provisions of the statute, no regulation adopted is valid or effective unless consistent and not in conflict with the statute and reasonably necessary to effectuate the purpose of the statute.
- 5 Subdivision (b) of 1 CCR 10 provides as follows: (b) In order to meet the "necessity" standard of Government Code section 11349.1, the record of the rulemaking proceeding shall include:
- (1) A statement of the specific purpose of each adoption, amendment, or repeal; and
- (2) information explaining why each provision of the adopted regulation is required to carry out the described purpose of the provision. Such information shall include, but is not limited to, facts, studies, or expert opinion. When the explanation is based upon policies, conclusions, speculation, or conjecture, the rulemaking record must include, in addition, supporting facts, studies, expert opinion, or other information. An "expert" within the meaning of this section is a person who possesses special skill or knowledge by reason of study or experience which is relevant to the regulation in question.
- 6 With respect to this issue, "persons directly affected" includes both the chiropractors who are directly subject to the regulation and the members of the public who would receive MUA treatment by those chiropractors. 1 CCR 16(b) defines who is "directly affected" by a regulation. 1 CCR 16(b)(1) applies the term to those who "legally required to comply with the regulation", which in this case would be chiropractors. 1 CCR 16(b)(3) applies the term to those who "derive from the enforcement of the regulation a benefit that is not common to the public in general." Any benefit of these regulations accrues to chiropractic patients who receive MUA, not to the public in general. Therefore, with respect to this rulemaking file, members of the public who receive MUA from chiropractors are also "persons directly affected" for purposes of the clarity standard of the APA.

7 Section 11349.1(a)

This regulation would amend Article 6 of the Board's regulations, which establishes requirements for continuing education for chiropractors. In summary, the regulation would:

- Authorize a licensed chiropractor to perform MUA;
- Require a chiropractor performing MUA to have completed a 32-hour MUA training course;
- Require retraining in MUA not less than every three years;
- Require MUA to be performed only in a licensed hospital or ambulatory surgery center;
- Require any patient receiving MUA from a chiropractor to have been evaluated and approved for the treatment by a licensed medical or osteopathic physician who is familiar with MUA;
- Require the chiropractor performing MUA to have malpractice insurance endorsed for MUA;
- Specify circumstances under which may be performed by a chiropractor who was trained in MUA prior to the effective date of the regulations;
- State that the regulation does not establish a chiropractic specialty or specialty certification; and
- Declare that a chiropractor who performs MUA without complying with the provisions of the regulation has committed unprofessional conduct.

OAL reviewed the regulation to determine whether or not it complies with the APA. The relevant APA requirements with respect to this regulation are Necessity, Authority, Clarity, and Consistency

(Government Code2 section 11349.1(a)(1) through 11349.1(a)(4)). In several specific provisions the regulation does not satisfy these APA requirements. The specific provisions and the associated APA requirements will be discussed individually below.

OAL disapproval of the regulation is based exclusively upon failure of the regulation to conform to the requirements of the APA and should not be interpreted otherwise. Specifically, OAL did not examine the basic question of whether MUA is within the lawful scope of the practice of chiropractic and OAL did not examine or evaluate any issues involving the Medical Practice Act (Business and Professions Code, Division 2, Chapter 5, beginning at section 2000)

SPECIFIC ISSUE ANALYSES

1. Consistency. The proposed regulation has the effect of creating two types of chiropractors, those who may lawfully perform MUA and those who may not. This provision of the regulation is inconsistent with section 7 of the Act, which provides that possession of a license to practice chiropractic "shall authorize the licensee to practice chiropractic in the State of California as taught in chiropractic schools or colleges." The Act clearly authorizes only one form of license to practice and that all licensees are authorized to practice chiropractic on an equal basis. This regulation is inconsistent with this provision of the Act since it defines a component of chiropractic practice that some licensees may perform but others may not. In so doing it is inconsistent with section 7 of the Act and, thus, fails to satisfy the consistency standard of the APA.

The regulation contains a specific provision saying that "this regulation does not establish a chiropractic specialty or specialty certification and a MUA-trained licensee may not use any related designation or title." The inclusion of this provision does not rescue the regulation from the one-form-of-license restriction of section 7 of the Act. Although this provision would prevent a chiropractor authorized by the regulation to perform MUA from advertising this as a specialty, it would not alter the fundamental fact that the regulation effectively creates two types of chiropractic license. A chiropractor who complies with the regulation is licensed to perform MUA. Although the licenses may appear identical, this provision in fact creates two forms of license. Despite the disclaimer in the regulation saying that it does not establish a chiropractic specialty, it does, in fact, create two categories of licensees – those who may lawfully perform MUA and those who may not. This is inconsistent with the provision of section 7 of the Act providing that all licensees are authorized to "practice chiropractic in the State of California as taught in chiropractic schools and colleges."

2. Authority. The Board cites Business and Professions Code section 1000-4(b), which is the codification of section 4(b) of the Act3, as the statute providing the authority to adopt this regulation. Section 4(b) grants the Board broad authority to adopt rules and regulations. This authority, however, is not unlimited. In particular, it requires the rules to be adopted in accordance with the provisions of the APA.

It is well-established law that an administrative agency may not, under the guise of its rule-making power, exceed the scope of its authority and act contrary to the statute which is the source of its power. *California Employment Commission v. Kovacevich* (1946) 27 Cal.2d 546, 553, 165 P.2d 917, 921. To be valid, administrative action must be within the scope of authority conferred by the enabling statutes. *American Insurance Association v. Garamendi* (2005) 127 Cal.App.4th 228, 236, 24 Cal.Rptr.3d 905, 910. This principle is embodied in section 11342.24. The principle is made specific in 1 CCR 14(c)(1)(A), which provides, in pertinent part, that "an agency's interpretation of its regulatory power, as indicated by the proposed citations to 'authority' or 'reference' or any supporting documents contained in the rulemaking record, shall be conclusive unless . . . the agency's interpretation alters, amends or enlarges the scope of the power conferred upon it."

The Board's interpretation of its power pursuant to section 4(b) of the Act does alter, amend, or enlarge the scope of power conferred upon it by the Act. As discussed above, Section 7 of the Act authorizes the Board only to issue "one form of . . . license" and provides that any licensee may "practice chiropractic . . as taught in chiropractic schools and colleges." By adopting this regulation and creating two categories of licenses and, thus, two categories of licensees, the Board has taken an action that enlarges upon its scope of power to issue "one form of . . . license." The regulation, therefore, fails to satisfy the authority requirement of section 11349.1(a)(2).

3. Necessity. The record presented with this regulation does not adequately establish the necessity for the proposed rule. In order for a regulation to be valid, the record of a rulemaking must demonstrate "by substantial evidence the need for a regulation to effectuate the purpose of the statute, court decision, or other provision of law that the regulation implements, interprets, or makes specific, taking into account the totality of the record," (section 11349(a)). This requirement is made specific in 1 CCR 10(b)5.

The record submitted to OAL does not adequately establish either the overall necessity for the regulation nor does it contain an adequate demonstration of the necessity for each provision. The Initial Statement of Reasons (ISOR) states that "presently there is no regulation in effect that would ensure patient protection during treatment of manipulation under anesthesia (MUA) and licensees performing the procedure." There is nothing in the file, such as evidence of actual harm, studies, expert opinion, or other information demonstrating the need for the regulation. The absence of a regulation is not evidence of need for a regulation.

In detailing the factual basis for the regulation, the ISOR indicates that "[i]nterest in MUA is increasing within the profession, and, thus, MUA procedures are being performed by a growing number of licensees." It goes on to cite the intent of the regulation to "minimize the likelihood of harm," and to "ensure the highest quality of care." All of the statements in the ISOR, however, are conclusions or statements of intent. There is no factual basis in the ISOR or elsewhere in the record demonstrating the actual need for the regulation.

Although the asserted need for the regulation is the protection of the public from inadequately trained chiropractors performing MUA, there is no evidence demonstrating that the current practices by chiropractors performing MUA presents a threat to public health. The file contains no supporting facts, studies, expert opinion, or other information for the conclusion that the regulation is necessary. Absent a stronger factual showing of the problem that motivates this regulation and an explanation of how the regulation corrects that problem, the rulemaking file as submitted fails to demonstrate necessity as required by the APA.

The record is also deficient in explaining the need for many of its specific provisions. Among these specific deficiencies are the following:

• The 32-hour requirement: The record contains no information indicating how the Board determined that 32 hours of training is required and

sufficient for a chiropractor to perform MUA;

- The 3-year retraining requirement: The record does not contain the facts upon which the Board concluded that retraining every 3 years is required and adequate;
- The evaluation requirement: The record contains no facts to demonstrate why evaluation of a potential MUA patient by a medical or osteopathic physician is required; and
- The malpractice insurance requirement: The record is silent as to why the regulation requires any chiropractor performing MUA to carry malpractice insurance endorsed for MUA.

With respect to this specific issue, OAL is not evaluating whether or not this regulation, or the specific individual components of the regulation, are in fact necessary. The necessity standard of the APA is a requirement that a showing of necessity be made. In this rulemaking record, the showing of necessity is inadequate. Based upon the record before us, this regulation lacks a factual basis to establish necessity pursuant to the APA.

4. Clarity. The APA requires regulations to be clear. The clarity standard is defined in section 11349(c) as "written or displayed so that the meaning of regulations will be easily understood by those persons directly affected by them." This definition is made specific in 1 CCR 16. Of particular relevance to this file is 1 CCR 16(a)(5), which provides that a regulation is not clear if it "presents information in a format that is not readily understandable by persons 'directly affected6'." The MUA regulation is not displayed in a manner that conforms to the clarity standard of the APA.

The regulation would add section 361 to Article 6 of Division 4 of Title 16 of the CCR. Article 6 is entitled "Continuing Education" in the CCR. The majority of the regulation under review deals with continuing education, but the regulation also contains significant provisions which are not related to continuing education. Among these provisions are:

- The explicit grant of authority for chiropractors to perform MUA;
- The requirement that MUA be performed only in a specified health facility;
- The requirement that a medical or osteopathic physician evaluate the patient before receiving MUA from a chiropractor;
- The requirement that a chiropractor performing MUA carry malpractice insurance endorsed for MUA;
- The "grandfather clause" for chiropractors who received training prior to the effective date of the regulation;
- The statement that the regulation does not create a chiropractic specialty; and
- The provision declaring violation of the regulation to be unprofessional conduct.

This display is fundamentally confusing. A person directly affected by this regulation would be unlikely to look to the Continuing Education article of the CCR to find substantive proposals such as these. In order to comply with the clarity standard, the regulation should not be placed in Article 6. As adopted by the Board, the regulation fails to satisfy the clarity standard of the APA with respect to clarity of display.

The requirement that a chiropractor performing MUA must carry "malpractice insurance with an endorsement for MUA" also fails to satisfy the clarity standard in that it doesn't identify the amount of insurance required. A chiropractor hoping to comply with this provision would be unable to determine how much coverage it took to comply.

THE PRACTICE OF MEDICINE AND THE USE OF DRUGS

One other significant issue, although not a factor in this disapproval, must be addressed in any resubmission of the regulation to OAL. This is the question of whether this regulation is consistent with the provisions of section 7 of the Act providing that a license to practice chiropractic "shall not authorize the practice of medicine, surgery, osteopathy, dentistry or optometry, nor the use of any drug or medicine now or hereafter included in materia medica." The record submitted to OAL with this regulation does not contain adequate information from which to evaluate this question.

The record contains public comment alleging that performance of MUA by a chiropractor constitutes the unlawful practice of medicine in violation of the Medical Practice Act. As indicated above, this disapproval is not based upon evaluation of that issue. The record before OAL is inadequate to complete this analysis. This is, however, a threshold issue. If the regulation is inconsistent with section 7 of the Chiropractic Initiative Act or with the provisions of the Medical Practice Act, it cannot be a valid regulation.

Due to the limited information provided in the file, OAL cannot evaluate whether the regulation improperly authorizes the practice of medicine. Should the Board elect to correct the deficiencies identified in this Decision of Disapproval and resubmit this regulation pursuant to section 11349.4, the record submitted must provide information adequate to demonstrate that the practice of MUA by a chiropractor is consistent with the Medical Practice Act and with the provision of section 7 of the Chiropractic Initiative Act, which provides that a license to practice chiropractic does not authorize the practice of medicine.

Also due to the limited information provided in the record, OAL cannot evaluate whether or not the regulation is consistent with the provision of section 7 of the Act providing that a license to practice chiropractic does not authorize "the use of any drug or medicine" in the practice of chiropractic. The rulemaking record demonstrates clearly that the regulation does not authorize a chiropractor to *administer* anesthesia. The Act, however, is broader than this. It prohibits the *use* of any drug or medicine in the practice of chiropractic. If the use of anesthesia is integral to the performance of MUA, and if anesthesia is a "drug", it is highly questionable whether the regulation is consistent with the Act's prohibition on "the *use* of any drug or medicine."

In the ISOR and elsewhere in the record, the Board states that section 302 of its regulations, which defines the practice of chiropractic contains "no prohibition on the use of anesthesia during . . . manipulations." This is true, but irrelevant. The issue which must be evaluated is not whether the Board has previously decided to prohibit the use of anesthesia by regulation. The relevant question is whether or not the Chiropractic Initiative Act and the Medical Practice Act permit the use of anesthesia in chiropractic treatment.

While it seems intuitively reasonable to conclude that MUA does, in fact, involve the "use of [a] drug," the rulemaking record is inadequate to determine this as a matter of law and the analysis conducted by OAL is restricted to the content of the rulemaking record?. The record submitted for our review contains inadequate information to support a definitive legal determination that the performance of MUA involves the "use" of a drug. Indeed, the record does not even define what MUA is. Should the Board elect to resubmit this regulation pursuant to section 11349.4, the record submitted should provide information

adequate to demonstrate that the practice of MUA does not violate the prohibition of section 7 of the Act against the use of any drug or medicine by a chiropractor.

CONCLUSION

As explained above, OAL disapproves the regulatory action for failure to comply with the consistency, authority, necessity, and clarity standards of the APA. If you have any questions, please do not hesitate to contact me at (916) 323-6221.

Director

DATE: October 11, 2005

WILLIAM L. GAUSEWITZ

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